

UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF WISCONSIN

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INNOGENETICS N.V.,  
a Belgian Corporation,

Plaintiff,

v.

Case No. 05-C-0575-C

ABBOTT LABORATORIES,  
an Illinois Corporation,

Defendant.

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INNOGENETICS' MOTION *IN LIMINE* TO EXCLUDE ANY TESTIMONY OF  
DR. BRUCE PATTERSON OR OTHER WITNESSES ON THE ISSUE OF  
OBVIOUSNESS, OR, IN THE ALTERNATIVE, TO EXCLUDE EXPERT OPINION  
TESTIMONY OF DR. PATTERSON, OR ANY OTHER ABBOTT WITNESS, ON  
ISSUES NOT DISCLOSED AND SUPPORTED IN DR. PATTERSON'S EXPERT  
INVALIDITY REPORTS

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MOTION

Plaintiff Innogenetics N.V. hereby moves, pursuant to Federal Rules of Civil Procedure 26(a)(2) and 37(c)(1) for an order *in limine* precluding the testimony by Dr. Bruce Patterson, or any other Abbott/Celera fact or "expert" witness, on the following issues relating to Abbott's allegations of obviousness of the patent claims of U.S. Patent No. 5,846,704 ("the '704 patent"):

- ***To preclude any evidence relating to the obviousness of any claim of the '704 patent*** – Dr. Patterson's invalidity reports contains several material omissions and/or errors relating to obviousness. First, they contains no discussion that any of the asserted combination references provide a ***reasonable expectation of success*** of making the claimed method. In fact, the words "reasonable expectation of success" are not found in his reports. Second, he provides no analysis for ***how to modify any of the prior art*** he cites, in view of any other art, to arrive at the method as claimed in the '704 patent. Rather, his obviousness analysis appears to rest entirely on an assumption that the asserted references actually anticipate the '704 patent claims. Third, the reference he cites in support of ***motivation to combine*** (Kanai 1992) provides no such motivation. Rather, Kanai 1992, at most, suggests the possible advantage of genotyping in order to understand patient response to drug therapy.

Kanai 1992 nowhere suggests, and Dr. Patterson does not contend otherwise, that such genotyping should or could be accomplished by combining one of the cited references with another to arrive at the methods claimed in the '704 patent. Finally, Dr. Patterson nowhere even mentions the *secondary indicia of non-obviousness* (in fact, he had never heard of the term when deposed).

In the alternative, Innogenetics moves for an order precluding Abbott from introducing any evidence relating to:

- ***Reasonable expectation of success*** – Even if Abbott is permitted to present testimony at trial on obviousness, neither Dr. Patterson nor any other Abbott/Celera witness should be permitted to testify at trial as to whether there was a reasonable expectation of success in arriving at the claimed methods. Dr. Patterson's invalidity reports are silent on the issue.
- ***How to combine the cited references*** – Even if Abbott is permitted to present testimony at trial on obviousness, neither Dr. Patterson nor any other Abbott/Celera witness should be permitted to testify at trial as to how the asserted references could be combined to arrive at the methods claimed in the '704 patent. Simply put – Dr. Patterson's invalidity reports nowhere state how any reference would be modified to arrive at the methods claimed in the '704 patent.
- ***Motivation to combine*** – Even if Abbott is permitted to present testimony at trial on obviousness, neither Dr. Patterson nor any other Abbott/Celera witness should be permitted to testify at trial as to how the prior art would have actually motivated a skilled artisan to combine any of the asserted references with another to arrive at the methods claimed in the '704 patent. Dr. Patterson's invalidity reports are silent on this issue.
- ***Secondary indicia of non-obviousness*** – Even if Abbott is permitted to present testimony at trial on obviousness, neither Dr. Patterson nor any other Abbott/Celera witness should be permitted to testify as to the secondary indicia of non-obviousness. Dr. Patterson's invalidity reports are silent on this issue, and Dr. Patterson professed no understanding of the term during his deposition, much less how it applied to an obviousness analysis of the methods claimed in the '704 patent. Abbott's decision not to address this issue – and not to educate its expert on it – is inexcusable given the fact that Abbott had twice been presented with Dr. Geert Maertens to testify on this topic in response to Abbott's 30(b)(6) deposition notice requesting such testimony.

## **MEMORANDUM OF POINTS AND AUTHORITIES**

### **I. Factual Background**

Abbott's expert, Bruce K. Patterson, M.D., provided an expert report entitled "Expert Report of Bruce K. Patterson, M.D. Regarding The Invalidity of Innogenetics, N.V.'s U.S. Patent

No. 5,846,704” (April 10, 2006) (dkt. 33) (“Patterson First Invalidity Report”). In the Patterson First Invalidity Report, Dr. Patterson provided certain opinions concerning anticipation and obviousness.<sup>1</sup>

Dr. Patterson subsequently submitted a second invalidity report, which alleged eight new grounds of anticipation. *See* Supplement to Expert Report of Bruce K. Patterson, M.D. Re Invalidity of Innogenetics’ ‘704 Patent (May 19, 2005) (dkt. 59) (“Patterson Supplemental Report”). Upon Innogenetics’ motion, however, the Court struck, in part, the Supplemental Report as not being provided for under the Court’s rules.<sup>2</sup> *See* Order Granting in Part and Denying in Part Plaintiff’s Mot. to Strike Supp. Expert Report of Dr. Patterson (Aug. 3, 2006) (dkt. 158).

In fact, as discussed below, Dr. Patterson’s invalidity reports do not make out a prima facie case of obviousness because, *inter alia*, Dr. Patterson has set forth no evidence to support Abbott’s affirmative burden to (1) prove that the prior art he asserts would have created a reasonable expectation of success of making the methods claimed in the ‘704 patent; (2) show how any of the prior art references would have been modified to arrive at the methods claimed in the ‘704 patent; (3) show how the motivation to combine the reference he cites (Kanai 1992) would have led the skilled artisan to combine one of the prior art references with another to arrive at the claimed invention; and (4) factor in the evidence relating to secondary indicia of

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<sup>1</sup> Dr. Patterson’s opinions concerning anticipation are the subject of a separate motion *in limine*. *See* Innogenetics’ Motion *In Limine* to Exclude Any Testimony of Dr. Bruce Patterson or Other Witnesses on the Issue of Anticipation, or, in the Alternative, to Exclude Expert Opinion Testimony of Dr. Patterson, or Any Other Abbott Witnesses, on Issues Not Disclosed and Supported in Dr. Patterson’s Expert Reports (filed herewith).

<sup>2</sup> The Court’s Order did permit Dr. Patterson to correct his initial mis-citation of a 1992 Kanai article in his report. *See* Order Granting in Part and Denying in Part Plaintiff’s Mot. to Strike Supp. Expert Report of Dr. Patterson, at 3.

non-obviousness. Indeed, Dr. Patterson's invalidity reports do not address, much less countermand, Innogenetics' evidence that there would have been no reasonable expectation of success in making the claimed invention and that the secondary indicia provide additional, strong evidence of non-obviousness.<sup>3</sup>

But the law of both the Federal Circuit and this Court is clear that Abbott's failure to provide evidence on these essential elements of prima facie obviousness is fatal to its obviousness defense. For transparent reasons, therefore, Abbott may try to elicit testimony from Dr. Patterson and/or from listed Abbott/Celera witnesses to fill the gaps in its case. However, Abbott should be precluded from "back-dooring" expert opinions on undisclosed subjects through other witnesses. For the reasons discussed below, therefore, this motion seeks to

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<sup>3</sup> As pointed out in Innogenetics' Corrected Memorandum In Opp. to Abbott Laboratories' Mot. for Summ. J. of Non-Infringement and Invalidity (June 8, 2006) (dkt. 77), at 61-62, these deficiencies were unsurprising given Dr. Patterson's absence of knowledge as to the legal requirements for proving anticipation. Indeed, Dr. Patterson acknowledged that his *entire* "interpretation" of anticipation was actually contained in "the title" on page 14 of his report:

Q. Am I right in my read of your report that the working definitions of anticipation and obviousness that you are relaying on this record are nowhere contained in the body of your report?

\* \* \*

A. No, in section 8, subsection A.

Q. Give me a page, please.

A. ***Page 14, the title includes my interpretation of anticipation*** and reads, "The Cha application disclosed and taught the methods of the 704 patent." Similarly, in section D --

Q. Just stop right there, disclosed and taught the methods, that is your definition of what?

A. Anticipation.

Q. ***And is this your articulation?***

A. ***Yes . . .***

Patterson Dep. Tr. (April 25, 2006) (dkt. 158), at 147:25-148:19 (emphasis added).

preclude or limit the testimony of Dr. Patterson, and to preclude the testimony of any other Abbott/Celera witness, concerning obviousness of the '704 patent claims.<sup>4</sup>

## II. Argument

### A. Federal Rules Of Civil Procedure 26 And 37 Serve To Protect Parties From Surprise Tactics And To Limit Prejudice Resulting Therefrom

Rule 26 of the Federal Rules of Civil Procedure is intended to encourage meritorious adjudication and protect parties from trial by surprise. When the provisions of Rule 26 are properly followed, the rule serves to “increase[] the quality of trials by better preparing attorneys for cross-examination, minimizing surprise, and supplying a helpful focus for the court’s supervision of the judicial process.” *Thibeault v. Square D Co.*, 960 F.2d 239, 244 (1st Cir. 1992) (citations omitted). Moreover, disclosure pursuant to Rule 26(a)(2) of experts and the topics on which they will opine “is necessary to allow the opposing party ‘a reasonable opportunity to prepare for effective cross examination and perhaps arrange for expert testimony from other witnesses.’” *Jacobsen v. Deseret Book Co.*, 287 F.3d 936, 953 (10th Cir. 2002) (quoting Fed. R. Civ. P. 26(a)(2) advisory committee note (1993)). This Court’s decisions are in complete accord. *See Frazier v. Layne Christensen Co.*, No. 04-C-315-C, 2006 U.S. Dist. LEXIS 49423, at \*21 (W.D. Wis. July 17, 2006) (where expert’s new opinions at trial have not been revealed under the Federal Rules of Civil Procedure, it is unfair for litigant “to be forced to

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<sup>4</sup> In this regard, Abbott designated, in its initial Proponent Expert Witness Disclosures, as expert and fact witnesses, Dr. Leckie, Dr. Smith and Dr. Zoccoli. *See* Declaration of Lissa R. Koop in Support of Innogenetics’ Motions *In Limine* (“Koop Decl.”), Ex. 5 (Abbott Laboratories’ Proponent Expert Witness Disclosures, dated April 10, 2006). Abbott has also stated that it intends to call Dr. Tai-An Cha as a witness and Innogenetics has filed a separate motion *in limine* to preclude Dr. Cha from testifying. *See* Innogenetics’ Mot. *In Limine* to Exclude the Testimony of Dr. Tai-an Cha and Any Expert Testimony of Dr. Thomas White (filed herewith).

defend against those new opinions on the critical issue in the case with no notice and no time to prepare.”)

It is well-settled that an expert may not present opinions at trial that were not properly and timely disclosed pursuant to Federal Rule of Civil Procedure 26(a)(2)(B). That rule requires that an expert witness submit a written report that, *inter alia*, “shall contain a complete statement of all opinions to be expressed and the basis and reasons therefor.” Rule 37(c)(1) provides that “[a] party that without substantial justification fails to disclose information required by Rule 26(a) . . . is not, unless such failure is harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed.”

To ensure compliance with the disclosure requirements imposed by Rule 26(a), courts are entrusted with “broad discretion” in determining whether exclusion of proffered testimony under Rule 37 is appropriate. *David v. Caterpillar, Inc.*, 324 F.3d 851, 856-57 (7th Cir. 2003). The Seventh Circuit has found proper the exclusion of expert testimony as to subject matter not disclosed in an expert’s report. *See, e.g., NutraSweet Co. v. X-L Eng’g Co.*, 227 F.3d 776, 785 (7th Cir. 2000) (“If a party does not timely file his reports, the district court may exclude the party’s expert from testifying at trial on the matters the party was required to disclose.”); *see also Briggs & Stratton Corp. v. Kohler Co.*, 398 F. Supp. 2d 925, 931 (W.D. Wis. 2005) (“When Rule 26 is violated, exclusion of any non-disclosed information is ‘automatic and mandatory unless the sanctioned party can show that its violation of Rule 26 was either justified or harmless.’” (quoting *David v. Caterpillar, Inc.*, 324 F.3d 851, 857 (7th Cir. 2003))).

**B. The Court Is Justified In Excluding from Trial Abbott’s Testimony On Obviousness Because Abbott Cannot As A Matter Of Law Present A Prima Facie Case.**

In a decision squarely on point, this Court granted judgment as a matter of law (“JMOL”) of no invalidity because the jury heard no evidence of a required element of a prima facie case of

obviousness, *i.e.*, reasonable expectation of success. *See Briggs & Stratton Corp. v. Kohler Co.*, No. 05-C-0025-C, 2006 U.S. Dist. LEXIS 35748, \*26 (W.D. Wis. May 30, 2006), where this Court held:

However, in order to find that a patent is invalid as obvious, a jury must find not only that one skilled in the art would have been motivated to combine elements from different prior art references, but also that he would have perceived a reasonable expectation of success in making the invention via that combination.

\* \* \*

Defendant contends that the ‘reasonable expectation of success’ requirement is not a clearly established element of obviousness and applies ‘mostly’ to cases involving chemical and biotechnical patents. As discussed above, the Court of Appeals for the Federal Circuit has held clearly that a finding of obviousness under § 103 requires both motivation to combine and a reasonable expectation of success. Defendant does not cite authority for the distinction it draws and none is readily ascertainable.

\* \* \*

At trial, . . . [t]he jury heard no evidence that one skilled in the art would have had a reasonable expectation of success if he were to combine the [cited art]. Without proof, it was not free to assume that this critical element was present. Therefore, plaintiff’s motion for judgment as a matter of law that the ‘166 patent is not invalid as obvious will be granted.

*Id.* at \*26-27 (citation and quotations omitted).

This Court’s recent decision in *Frazier* is also remarkably on point. There, like here, the Court was confronted with an expert who “did not understand what obviousness means in the context of patent law.” *Frazier*, 2006 U.S. Dist. LEXIS 49423 at \*13. As a result, Plaintiff’s expert report contained no discussion of reasonable expectation of success or analysis of how the references could or could not be combined. Upon deciding to strike the Plaintiff’s expert’s faulty testimony in full, the Court found for the Defendant because its evidence on the issue of obviousness “would have stood unchallenged.” *Id.* at \*22.

Given the Court’s inherent authority to take such action as a matter of law *after trial* when presented with legally insufficient proofs relating to obviousness, the Court is well within its authority to preclude *before trial* the same incomplete proof given the absence in the

Patterson invalidity reports of any mention of reasonable expectation of success or how the cited references could be combined to arrive at the methods claimed in the '704 patent.

**C. Having Failed To Proffer Any Opinion Concerning Reasonable Expectation Of Success, Specific Combinations Of References, Specific Motivation, And Secondary Indicia Of Non-obviousness, Abbott Should Be Precluded From Arguing Obviousness Because It Cannot Make Out A Prima Facie Case.**

As discussed above, it is black letter law that a party alleging obviousness must establish “not only that one skilled in the art would have been motivated to combine elements from different prior art references, but also that he ‘would have perceived a reasonable expectation of success in making the invention via that combination.’” *Briggs & Stratton Corp.* 2006 U.S. Dist LEXIS 35748, at \*21. Having failed to opine regarding reasonable expectation of success in his invalidity reports, Dr. Patterson will be unable opine about it at trial. Hence, Abbott cannot adduce testimony at trial concerning one of the required elements of a prima facie case of obviousness.

Similarly, Dr. Patterson also failed to present any testimony concerning specific combinations of references or modifications which could be made to one reference, based on the teaching and motivation from other references, to arrive at the methods recited in the claims of the '704 patent. Rather, Dr. Patterson provided a substantially identical statement regarding the combination of references for each claim:<sup>5</sup>

***Given these known methods for genotyping*** using the 5'-UT and the motivation provided by Kanai, the 1992 Cha Article and the Okamoto Reference (see above at Section VIII.D.) ***to apply known HCV genotyping methods*** for therapeutic reasons, to one skilled in the art it would have been obvious to perform the genotyping method in claim 1 and of the '704 patent.

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<sup>5</sup> Only the recitation at the end of the obviousness analysis for claim 2 was different, and that was only by the addition of the phrase “which requires using at least two probes simultaneously that hybridize to the claimed region.” Patterson First Invalidity Report at 24-25.



Patterson First Invalidity Report at 24.

Dr. Patterson's obviousness "analysis" thus appears to be nothing more than a re-styled anticipation defense ("[g]iven these known methods for genotyping. . ." and the motivation "to apply known HCV genotyping methods"). In other words, because the references teach "known methods for genotyping," therefore they also render obvious the claims. But this begs the question: *what* known methods of genotyping? In any event, merely opining that claims are obvious because they are anticipated does not support a separate case of obviousness and does not entitle Abbott to present its anticipation arguments a second time under the guise of obviousness.

Further, the reference to support motivation to combine provided by Dr. Patterson is a letter to the editor of a journal in which Dr. Kanai suggested the possibility that genotyping may be an important factor in determining interferon response in chronic HCV patents. *See* Patterson Supplemental Report, Ex. A. While this observation is undisputed, it does not provide motivation to combine or modify any of the cited references as suggested by any of the other cited references to arrive at the methods claimed in the '704 patent. Any specific motivation to combine one of the cited references with another is simply lacking.

Finally, it is undisputed that Dr. Patterson had not factored in the secondary indicia of non-obviousness into his analysis. Indeed, he professed to have no idea what the phrase meant in his first deposition:

Q. . . . Are you aware of a case by the name of Graham versus John Deere?

A. No.

Q. Have you ever heard of the concept of secondary indicia of non-obviousness?

A. No.

Q. Have you employed considerations relating to non-obviousness conditions in your report?

A. Not that I know of.

Q. And is it true that you were not asked to address that issue?

A. I've never been asked in that way to address that.

Q. Do you know generally how contentions of obviousness can be overcome under United States patent law?

A. It's not my field of expertise.

Patterson Dep. Tr. at 149:14-150:3.

This failure on the part of Abbott to consider the issue or educate its expert on it is inexplicable, especially given the fact that, in response to *Abbott's* Notice under Fed. R. Civ. P. 30(b)(6), Innogenetics prepared and tendered Dr. Geert Maertens *twice* for deposition. Although secondary indicia of obviousness may not be outcome determinative in and of themselves, they are plainly an important and necessary part of any obviousness analysis:

The last factor, collectively known as the objective indicia of non-obviousness, or secondary considerations, requires the jury to consider any evidence showing, for example, (1) that the claimed invention has achieved commercial success; (2) an unfilled, but long-felt need in the industry for the invention; (3) that others in the industry have copied the claimed invention; (4) that others in the industry have previously failed to solve the problem addressed by the claimed invention; and (5) that the claimed invention achieved unexpected results. The Federal Circuit has noted that this type of evidence 'may often be the most probative and cogent evidence in the records.' *Ruiz*, 234 F.3d at 667-68.

ABA Model Jury Instruction 9.7; Obviousness — Introduction. Because Abbott failed to support its invalidity defense during ten months of discovery, it should be precluded from being allowed to do so at trial.

**D. Even If Abbott Is Permitted To Raise Obviousness At Trial, Neither Dr. Patterson Nor Any Other Abbott/Celera Witness, Should Be Permitted To Testify Concerning Reasonable Expectation Of Success, Specific Combinations Of Prior Art, Specific Motivation To Combine And/Or Secondary Indicia Of Non-obviousness.**

As discussed above, Abbott has adduced no evidence concerning the issues of reasonable expectation of success, specific combinations of prior art, specific motivation to combine and/or secondary indicia of non-obviousness. In the event that Abbott is permitted to present an obviousness case at trial, then at a minimum, Abbott should be precluded from proffering new opinions on these issues, whether through Dr. Patterson or other Abbott/Celera witness. Such new opinions would be manifestly prejudicial to Innogenetics, which then would be forced to cross-examine and rebut such new opinions “on the fly” at trial. *See Frazier*, 2006 U.S. Dist. LEXIS 49423 at \*21 (where expert’s new opinions at trial have not been revealed under the Federal Rules of Civil Procedure, it is unfair for litigant “to be forced to defend against those new opinions on the critical issue in the case with no notice and no time to prepare.”)

**CONCLUSION**

For the reasons set forth above, Abbott has not proffered a prima facie case of obviousness in its expert report and thus should be precluded from presenting testimony on obviousness at trial. In the event that the Court permits Abbott to present an obviousness case at trial, then any attempt by Abbott to deviate from or supplement the grounds of obviousness set forth in the Patterson First Invalidity Report – whether by Dr. Patterson or any Abbott/Celera fact witness – should be precluded.

Dated this 10th day of August, 2006.

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